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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/285,632	04/02/1999	NATHANIEL T. BECKER	GC530-2	3949

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11/18/2002

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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 11/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/285,632

Applicant(s)

BECKER ET AL.

Examiner

Susan Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-27, 41, 42, 46-48, 50-56 and 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-27, 41, 42, 46-48, 50-56 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time and Request for Continued Examination filed 06/04/02, and Election filed 09/04/02.

Election/Restrictions

Applicant's election with traverse of Group I (claims 22-27, 41, 42, 46-48, 50-56, and 58) in Paper No. 26 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 57, 59-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 26.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-27, 41, 42, 46-48, 50-56, and 58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. While applicant's specification preferred the use of modified starch and

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cellulose in the coating, it appears that applicant's specification does not provide support for the limitation "the coating does not contain a water insoluble polymer." It appears that the purpose of the amended limitation is to exclude the prior art. The introduction of claim changes, which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. In *Ex parte Ohshiro*, 14 USPQ2d 1750 (Bd. Pat. App. & Inter. 1989), the Board affirmed the rejection under 35 U.S.C. 112, first paragraph, of claims to an internal combustion engine which recited "at least one of said piston and said cylinder (head) having a recessed channel." The Board held that the application, which disclosed a cylinder head with a recessed channel and a piston without a recessed channel did not specifically disclose the "species" of a channeled piston.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-26, 41, 46-48, 50-54, and 58 rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. US 5,356,467.

Oshlack teaches controlled release coating composition comprising zein, water soluble plasticizer, and mixture of rate-controlling agents, including water soluble

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hydrophilic polymers and modified starch (columns 4-5, and 7-9). The coating is useful for coating agricultural, food, household products, and pharmaceutical, e.g., tablet core, granule, microspheres, seeds, pellets, or beads (column 7, lines 28-40).

The examiner notes that the reference briefly mentions the combination of hydrophobic acrylic polymer as a pore-former, with no further indication or explanation as to its function. However, omission of an element and its function is obvious if the function of the element is not desired. *Ex parte Wu*, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989) (Claims at issue were directed to a method for inhibiting corrosion on metal surfaces using a composition consisting of epoxy resin, petroleum sulfonate, and hydrocarbon diluent. The claims were rejected over a primary reference which disclosed an anticorrosion composition of epoxy resin, hydrocarbon diluent, and polybasic acid salts wherein said salts were taught to be beneficial when employed in a freshwater environment, in view of secondary references which clearly suggested the addition of petroleum sulfonate to corrosion inhibiting compositions. The Board affirmed the rejection, holding that it would have been obvious to omit the polybasic acid salts of the primary reference where the function attributed to such salt is not desired or required, such as in compositions for providing corrosion resistance in environments which do not encounter fresh water.). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965) (Omission of additional framework and axle which served to increase the cargo carrying capacity of prior art mobile fluid carrying unit would have been obvious if this feature was not desired.); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (deleting a prior art switch member and thereby eliminating its function was an obvious

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expedient). Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation omit the hydrophilic polymer where the function attributed to such polymer is not desired or required.

Claims 22-27, 41, 42, 46-48, 50-56, and 58 rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al. US 5,639,476.

Oshlack teaches a pharmaceutical formulation in the form of tablets, beads, seeds, or granules that can be coated with a coating composition comprising water-soluble hydrophilic polymers (column 10, lines 45-06), modified starch (column 11, lines 12-41), and plasticizer (column 12, lines 29 through column 14, lines 1-40).

The examiner notes that the reference teaches the use of hydrophobic acrylic polymer in certain preferred embodiments. However, applicant has not provided any comparative data showing that the presence of the hydrophobic acrylic polymer would have a detrimental effect upon the desirability to obtain a useful coating composition. Hence, it would have been *prima facie* obvious for one of ordinary skill in the art to, by routine experimentation modify Oshlack's coating composition with the expectation of at least similar result, because Oshlack recognizes the properties of modified starch and cellulose in coating composition useful for the same purpose desired by the applicant, e.g., coating composition for cleansing agent, therapeutic active agent, fertilizing agent, or disinfecting agent.

Regarding to claim 42, Oshlack is silent as to the disclosing of enzyme. However, Oshlack teaches a cleansing agent including deodorant, surfactant,

germicide, and sanitizer. Hence, it would have been prima facie obvious for one of the ordinary skill in this art to, by routine experimentation determine a suitable cleansing agent including enzyme. The reason for this modification is to obtain a stable coated composition that is useful in the pharmaceutical and cosmetic arts.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bastin et al., and Bechard are cited as being of interest for the teaching of coating composition.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


THURMAN K. PAGE
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